REMARKS

The Official Action dated January 14, 2004 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, the specification has been amended to recite related application information. The previously pending claims 40-84, 86-106 and 108-110 are canceled and claims 111-162 are presented herein. Claims 111-121 and 123-156 contain limitations from original claims 40-84, with various changes for form having been made in accordance with customary U.S. practice. Claim 122 contains limitations from original claim 50, while claims 157-160 contain limitations from original claims 42, 44, 46 and 53, respectively. Support for claims 161 and 162 may be found in the specification, for example at pages 19-20. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, the Examiner made the Restriction Requirement final. Accordingly, the present claims are directed to the elected subject matter of previous claims 40-84 and 108-110.

The Examiner objected to claims 75 and 76 as being in improper form and to claim 48 as containing language inconsistent with claim 47. Claims 119, 147 and 148, which contain limitations from original claims 48, 75 and 76, overcome the informalities noted by the Examiner. Reconsideration is respectfully requested.

The Examiner suggested that the application should include reference to the prior application. A related application section has been provided referring to the parent application and the provisional application of which priority is claimed.

Claims 50 and 77 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In claim 50, the Examiner objected to the recitation of both a broad range and a narrow range and in claim 77, the Examiner objected to the phrase "as defined". This rejection is traversed. More particularly, claims 121 and 122 are now presented to recite the broad and narrow ranges, respectively, originally presented in claim 50. Additionally, claim 149, which contains limitations from original claim 77, recites "a predetermined functional property of the container or its content", which is defined in the present specification at page 22, lines 9-12, and the phrase objected to the Examiner has been omitted. It is therefore submitted that these claims are definite in accordance with the requirements of 35 U.S.C. §112, second paragraph, and the rejection has been overcome. Reconsideration is respectfully requested.

Claims 77-80 and 84 were rejected under 35 U.S.C. §102(e) as being anticipated by the Walker et al U.S. Patent No. 5,651,775. The Examiner asserted that Walker et al disclose a method for operating a preparation delivery device comprising a container with an opening, a mechanism operable to deliver a preparation through the opening, attachment means and a sensor system which comprises transmitting radiation towards the container position and receiving at least part of the affected radiation. The Examiner specifically referred to Figure 1 and referred to Figure 10 as teaching detection of a functional property, namely plunger position, via detector 280.

However, Applicants submit that the methods defined by claims 149-152 and 156 are not anticipated by and are patentably distinguishable from the teachings of Walker et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, as defined by claim 149, the present invention is directed to a method for operating a preparation delivery device. The delivery device comprises a) a container for the

preparation having, or being prepared for the arrangement of, an opening, b) a mechanism operable to deliver at least part of the preparation in the container through the opening, c) attachment means for connection of the container to the mechanism, and d) a sensor system arranged to detect at least one predetermined property of the container or its content. The method comprises transmitting radiation towards a container position or a part thereof to allow the radiation to be affected by the container position, receiving at least a part of the affected radiation, and comparing the characteristics of the received radiation with a predetermined characteristic representative of a predetermined functional property of the container or its content, to establish if the predetermined functional property of the container or its content is present and thereby verify a status of the container acceptable for use.

The present methods provide a solution to the contradictory requirements between the need for sophisticated delivery devices to provide safety to and avoid misuse by nonmedical personnel, while allowing use of small and convenient devices which do not encumber daily use. More particularly, the present methods provide reliable operation of a preparation delivery device, which is not easily manipulated for either intended or unintended misuse. Importantly, the method of claim 149 not only requires transmitting radiation and receiving the part of the radiation affected by the container position, the method further comprises comparing the characteristics of the received radiation with a predetermined characteristic representative of a predetermined functional property of the container or its content to establish if the predetermined functional property of the container or its content is present. The method thereby verifies a status of the container acceptable for use.

As set forth in the present specification, a functional property is understood as any characteristic of an object not applied to transfer information to the device but is present for the

intended operational purpose of the device or as the result of the object manufacturing or use history (specification, page 22, lines 8-12). The functional property is contrasted with marked information brought to a device by separate information strip, i.e., a label (specification, page 22, lines 3-9).

Applicants find no teaching or suggestion of such a method by Walker et al. Walker et al disclose a medication delivery and monitoring system and methods suitable for use, for example, in a hospital. As set forth in the abstract, the Walker system is directed to methods for safely delivering drugs to a patient, monitoring real-time during delivery, and recording crucial events during delivery or providing real-time, online information and detail for an audit trail. The Walker et al system is therefore similar to that described in the background portion of the present application at page 1, lines 20-26. That is, the system and methods of Walker et al are designed for hospital treatment situations where there are few design restrictions and highly sophisticated equipment and techniques are employed. On the other hand, the present methods are particularly suitable for employing self-contained devices allowing safe use by patients.

The system set forth in Figure 1 relied upon by the Examiner includes a scanning and recording module 99. However, this scanning and recording module comprises a patient and procedure storage mechanism 100 for magnetically or otherwise printing data upon a portable data card 110 and a hard copy printer 120. A lamp 140 is provided for illumination of the device and is not for providing affected radiation to the recording module 99. In Figs. 10 and 11, Walker et al disclose a scanner module 242 including a scanning device 280 used to monitor the position of a plunger 282 associated with the syringe 50. The device 280 is seen to be a linear array detector. From the container label, information is provided to a system controller relative to syringe size which permits a real-time determination of a volume of fluid delivered or retrieved

from a patient as the syringe plunger 282 is moved within the syringe (see the specification at column 7, line 58 - column 8, line 42).

As discussed above, the method defined by claim 149 comprises not only transmitting radiation and receiving a part of the radiation affected by the container position, the method further comprises comparing the characteristics of the received radiation with a predetermined characteristic representative of a predetermined functional property of the container or its content to establish if the predetermined functional property of the container or its content is present and thereby verify a status of the container acceptable for use. Applicants find no such teaching by Walker et al; to the contrary, Walker et al are directed to the different objective of monitoring real-time during delivery of a medication with the scanning device 280. Particularly, Applicants find no teaching or suggestion by Walker et al of a method for comparing characteristics of received radiation with a predetermined characteristic representative of a predetermined functional property to establish if the predetermined functional property is present, to thereby verify a status of the container acceptable for use.

While Walker et al describe that bar code data of a syringe label cradle (SLC) unit 231 is read and a microcontroller 302 is programmed to check the name of the drug derived from the bar code data and sound an alarm if a problem is determined, such bar code data does not constitute a functional property of the container or its content as defined in the present application and claims. As noted above, the functional property is a characteristic present for the intended operational purpose of the device or as a result of the object manufacturing or use history, and is not merely information applied via a label, i.e., bar code data. Applicants find no teaching or suggestion by Walker et al relating to any comparison of characteristics with a predetermined characteristic

representative of a predetermined functional property, or any method using such to verify the status of a container acceptable for use.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q. 2d 1949, 1950 (Fed. Cir. 1999). In view of the failure of Walker et al to teach a method including a comparison step as recited in claim 149, employing a predetermined functional property to verify a status of the container acceptable for use, Walker et al do not disclose each and every element as set forth in claim 149, or claims 150-152 and 156, and therefore do not anticipate these claims under 35 U.S.C. §102. It is therefore submitted that the rejection under 35 U.S.C. §102 based on Walker et al has been overcome. Reconsideration is respectfully requested.

Claims 40-42, 44, 45, 49-57, 64, 65, 67-71, 73-76, 81-83, 108 and 109 were rejected under 35 U.S.C. §103 as being obvious and unpatentable over Walker et al in view of the Goldman U.S. Patent No. 5,750,998. The Examiner relied on Goldman as teaching the transmitting of radiation, receiving at least part of the affected radiation and comparing the characteristics of the received radiation to a predetermined characterization representative for a predetermined property to establish whether or not the predetermined property of the container is present, namely spectroscopic analysis. Claims 43, 46-48 and 110 were rejected 35 U.S.C. §103 as being obvious and unpatentable over Walker et al in view of Goldman and further in view of the Manique et al U.S. Patent No. 5,523,560. The Examiner relied on Manique as teaching the rotation of a container to create a two-dimensional image of its contents. Finally, claims 58-63, 66 and 72 were rejected 35 U.S.C. §103 as being obvious and unpatentable over Walker et al in

view of Goldman and further in view of the Carmen et al U.S. Patent No. 4,924,088. The Examiner relied on Carmen as disclosing the provision of markings 50 on an object.

However, Applicants submit that the methods defined by claims 110-162 are nonobvious over and patentably distinguishable from Walker et al and Goldman, alone or in further combination with either Manique et al or Carmen et al. Accordingly, these rejections are traversed and reconsideration is respectfully requested.

The method defined by claim 149, and claims 150-156 dependent thereon, has been discussed in detail above. Claim 111, and claims 112-148 and 157-162 dependent thereon, are similarly directed to a method for operating a preparation delivery device similarly comprising a container, a delivery mechanism, an attachment means and a sensor system. According to claim 111, the method comprises transmitting radiation toward a container position or a part thereof to allow the radiation to be affected by the container position, receiving at least a part of the affected radiation from at least an area part of the container position in a non-imaging way, and comparing the characteristics of the received radiation with a predetermined characteristic representative for the predetermined property to establish whether or not the predetermined property of the container is present.

The deficiencies of Walker et al with respect to the method of claim 149 are discussed in detail above. The teachings of Walker et al are equally deficient with respect to the method of claim 111. That is, in the method of claim 111, at least a part of the affected radiation from at least an area part of the container position is received in a non-imaging way. As described in the present specification, a non-imaging system is understood as a system designed to respond with a unified or single signal to the total radiation received from an area of the object and has the advantage of a strong simplification of the sensor system while providing adequate control results

(page 14, lines 15-29). The non-imaging system allows de-focus radiation to be employed which, in turn, allows the system to register a composite fingerprint response of the object part observed, providing a highly unique signal which is difficult to mimic, particularly if registered in the non-visible frequency range (see, for example, the specification at page 15, lines 4-12). On the other hand, Applicants find no teaching or suggestion by Walker et al relating to a method wherein at least a part of transmitted affected radiation from at least an area part of the container position is received in an non-imaging way, or the improvements provided thereby in a preparation delivery device operation method as presently claimed.

The deficiencies of Walker et al with respect to the methods of claims 111 and 149 are not resolved by any of the secondary references cited by the Examiner. First, Applicants find no teaching or suggestion in Walker et al or any of Goldman, Manique et al and Carmen et al for combining their teachings along the lines asserted by the Examiner. It is well established that the Examiner cannot pick and choose among the individual elements of assorted prior art references to recreate the claimed invention; rather, the Examiner has the burden to show some teaching or suggestion in the references to support their use in the particular claimed combination, *SmithKline Diagnostics, Inc. v. Helena Labs., Corp.*, 8 U.S.P.Q. 2d 1468, 1475 (Fed. Cir. 1988), *Symbol Technologies, Inc. v. Opticon*, 19 U.S.P.Q. 2d 1241, 1246 (Fed. Cir. 1991). The Examiner has not met the requisite burden with respect to the asserted combinations of references. Not only do the references themselves provide no teaching or suggestion motivating the asserted combinations, these references are directed to different fields of art, as indicated by their classifications, fields of search, and the problems to which these references are directed, whereby one skilled in the art would have had no motivation to combine their teachings.

For example, Goldman discloses a method and apparatus for non-invasively identifying components of liquid medium within a bag, for example, of parenteral nutrients. As described at column 6, beginning at line 43, Goldman employs spectroscopy to identify the liquid medium. One skilled in the art would have no motivation to combine the spectroscopy methods of Goldman with the real-time medication delivery monitoring methods of Walker et al, absent a hindsight view of the presently claimed methods. Moreover, Applicants find no teaching or suggestion by Goldman for receiving affected radiation in a non-imaging way as required by claim 111 or for comparing received radiation with a predetermined characteristic representative of a predetermined functional property to verify a status of a container acceptable for use as required by claim 149. Thus, Goldman does not resolve the deficiencies of Walker et al.

Manique et al disclose a method and apparatus for inspecting liquid filled containers, for example in the manufacture of cartridges or vials containing liquid pharmaceuticals for quality control purposes. Applicants find no teaching or suggestion by Manique et al relating to operating delivery devices, and particularly relating to a method as recited in claim 111, wherein at least a part of affected radiation is received in a non-imaging way, or a method as recited in claim 149, wherein the characteristics of received radiation are compared with characteristics representative of a predetermined functional property to establish the presence of the functional property and verify the status of a container acceptable for use. Thus, Manique et al do not resolve the deficiencies of Walker et al.

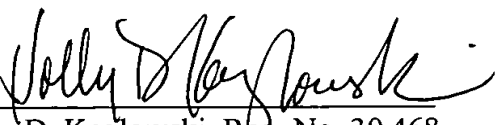
Finally, Carmen et al disclose an apparatus for reading information marks manually placed on objects or wood products using a photoelectric eye, strobe and detector, particularly for reading fluorescent information marks in the wood products industry. Applicants find no teaching or suggestion by Carmen et al relating to methods for operation of a preparation delivery

device, or for resolving the deficiencies in the teachings of Walker et al. Again, absent the hindsight view of the present application, one of ordinary skill in the art would have no motivation for combining the apparatus of Carmen et al, disclosed for use in the wood industry, with the real-time medication delivery monitoring system of Walker et al. Thus, Carmen et al do not resolve the deficiencies of Walker et al.

It is therefore submitted that the methods as defined by claims 110-162 are nonobvious over and patentably distinguishable from the asserted combinations of Walker et al and Goldman, alone or in combination with Manique et al or Carmen et al, whereby the rejections under 35 U.S.C. §103 have been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the objections and rejections under 35 U.S.C. §§102, 103 and 112, second paragraph, and places the application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

By 

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